UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte KENNETH F. BUECHLER, JOSEPH M. ANDERBERG,
and PAUL H. MCPHERSON

Appeal 2007-1034[1]
Application 09/712,615
Technology Center 1600

DECIDED: June 21, 2007

Before TONI R. SCHEINER, DONALD E. ADAMS, and RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellants appeal under 35 U.S.C. § 134 from a final rejection of claims 27, 28, and 93-128, all the claims remaining in the application. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

"Reliability in an immunoassay system is critical for the accurate measurement of [an] analyte" (Spec. 2: 5-6). The Specification describes

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[1] Heard May 17, 2007.

the concept of an independent assay control (IAC), which generates an optical signal independent of any signal generated by the analyte, and which can be used to correct or calibrate assay results, or to confirm various assay parameters, e.g., non-specific binding, flow mechanics, incubation time, assay progress, and time of completion, etc. (*id.* at 10: 6-15 and 12: 29).

The claimed invention is directed to an apparatus comprising an optical component configured to provide independent verification that a specific-binding assay has run to completion, regardless of the presence or amount of the analyte. Claim 27 is representative:

27. An apparatus for measuring progress and time of completion of an assay for an analyte, comprising:

(a) an assay device comprising:

(i) a reaction chamber comprising an optically detectable label, and

(ii) at least one diagnostic lane comprising at least one assay zone configured to bind said analyte and at least one timing zone separate from the assay zone, wherein said diagnostic lane is in fluid communication with said reaction chamber, and wherein, when fluid is added to said reaction chamber, said detectable label flows with said fluid to said at least one diagnostic lane to contact at least one timing zone;

(b) an optical component configured to detect an optical signal generated from said label in said at least one timing zone and generate an electronic signal in response; and

(c) a signal processor configured to receive said electronic signal and to determine said progress and time of completion of said assay for said analyte in said assay device from at least one parameter selected from the

group consisting of a rate of change of the amount of said electronic signal and an amount of said electronic signal.

The Examiner relies on the following references:

Foster	US 4,444,879	Apr. 24, 1984
Van Deusen	US 5,132,097	Jul. 21, 1992
Slovacek	US 5,242,837	Sep. 7, 1993
Buechler	US 5,458,852	Oct. 17, 1995

The claims stand rejected[2] as follows:

- Claims 27, 28, and 93-128, under 35 U.S.C. § 112, second paragraph, as indefinite.
- Claims 27, 28, and 93-128, under 35 U.S.C. § 112, first paragraph, as incorporating new matter.
- Claims 27, 93, 94, 96, 99, 100, 109-116, 118, and 121-126, under 35 U.S.C. § 103(a) as unpatentable over Buechler and Van Deusen.
- Claims 95 and 117, under 35 U.S.C. § 103(a) as unpatentable over Buechler, Van Deusen, and Slovacek.
- Claims 28, 101, 102, 104, 107, 108, 127, and 128, under 35 U.S.C. § 103(a) as unpatentable over Buechler, Van Deusen, and Foster.
- Claim 103 under 35 U.S.C. § 103(a) as unpatentable over Buechler, Van Deusen, Foster, and Slovacek.

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[2] The Examiner has indicated that "[c]laims 97, 98, 105, 106, 119, and 120 are objected to as being dependent upon a rejected base claim" (Answer 9), but otherwise allowable. This is inconsistent with the Examiner's continued rejection of these claims under 35 U.S.C. § 112, first and second paragraphs.

DISCUSSION

While the claims are rejected on several grounds, for all practical purposes, the issues raised by all of the rejections concern the "timing zone" (recited, e.g., in claim 27, clause (a)(ii)), and its structural and spatial relationships with other components of the claimed apparatus.

The Invention

The invention of representative claim 27 is an apparatus comprising an assay device. The assay device, in turn, comprises a reaction chamber, which includes an optically detectable label, in fluid communication with at least one diagnostic lane. Each diagnostic lane, in turn, comprises at least one assay zone, configured to bind an analyte of interest, and a separate timing zone. Because the reaction chamber is in fluid communication with the diagnostic lane(s), fluid added to the reaction chamber during the course of an assay carries the optically detectable label to the diagnostic lane(s), i.e., to the timing zone(s) and the assay zone(s).

The apparatus of claim 27 also includes an optical component configured to detect the signal generated by the optically detectable label in the timing zone(s), and generate an electronic signal in response. The apparatus further includes a signal processor configured to receive the electronic signal, and determine the progress and time of completion of the assay.

According to the Specification, measurement of the optical signal in the timing zone (i.e., the timing signal) provides an independent assay control (IAC) (Spec. 2: 20-22, and 40: 9 to 41: 15), which is not dependent on "the presence or amount of analyte but [is] dependent on the matrix of the

sample and the progress of the immunoassay process in the assay device" (*id.* at 31: 27-29). Thus, the signal from the IAC in the timing zone, which may be measured as "a rate of change of the amount of signal" or "an absolute amount of the signal" (*id.* at 13: 14-15), "defin[es] the status and the time of completion of an immunoassay in an assay device" (*id.* at 31: 19-20), whether or not analyte is present.

Further according to the Specification, the assay signal and the IAC signal (i.e., the timing signal) "can be measured in separate discrete zones" (Spec. 15: 28-29). "A particularly preferred location in the device for measuring the timing signal is at the end of the diagnostic lane . . . because the end of the diagnostic lane is the last to be washed of unbound label. Therefore, when the end of the diagnostic lane is free of unbound label, the beginning of the diagnostic lane, that is, closest to the reaction chamber, is also free of unbound label" (*id.* at 41: 11-15). Moreover, "[t]he discrete zones . . . may exist in different capillary tubes of an assay device" as well (*id.* at 15: 28-30).

Indefiniteness

The Examiner rejected all of the pending claims as indefinite under 35 U.S.C. § 112, second paragraph, as vague and indefinite because "the term 'timing zone' is a relative term" (Answer 3), and "it is not clear as to what the term is to encompass" (*id.*). In addition, the Examiner finds that the relationship between the timing zone(s) and the assay zone(s) "is not recited" (*id.* at 4), and "the label does not clearly bind to either of the zones to produce a detectable product" (*id.*). We will reverse this rejection.

Claim language must be analyzed "not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary skill in the pertinent art." *In re Moore*, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971). "A claim is not 'indefinite' simply because it is hard to understand when viewed without benefit of the specification." *S3 Incorporated v. NVidia Corp.*, 259 F.3d 1364, 1369, 59 USPQ2d 1745, 1748 (Fed. Cir. 2001).

As is evident from the many scenarios described in the Specification, the timing zone is a location in the claimed device where an optical signal from an independent assay control (IAC) (see e.g., Spec. 2: 20-22, 31: 27-29, and 40: 9 to 41: 15) is monitored to determine whether an assay has run to completion (*id.*). The determination may be based on the rate of change in signal intensity, or on absolute signal intensity (*id.* at 13: 14-15). The assay and timing zones are independent of each other, and in the case of the assay device of claim 27, physically discrete (i.e., separate) (*id.* at 15: 28-29, and 41: 11-15). Again, as explained in the Specification, the assay and timing zones may be at different locations in the same diagnostic lane, or they may even be in different capillary tubes in the same device (*id.* at 15: 28-30). Finally, the Specification teaches that the device may be monitored for optically detectable label bound to the timing zone, or simply flowing through it (*see id.* at 71: 4-6).

We find that the claims are not indefinite when read in light of the Specification, and the rejection of the claims under 35 U.S.C. § 112, second paragraph, is reversed.

New Matter

Claims 27, 28, and 93-128 stand rejected under 35 U.S.C. § 112, first paragraph, "as containing subject matter which was not described in the specification in such a way as to reasonably convey . . . that the inventor(s), at the time the application was filed, had possession of the claimed invention" (Answer 4). According to the Examiner, "[t]he disclosure does not show support for" a "device/apparatus with at least one timing zone separated from the assay zone" (Answer 4).

On the contrary, we find that the concept of an independent, and physically discrete (i.e., separate) timing zone is found throughout the Specification, both in the general discussion of IACs and in specific examples relating to timing zones. Example 15, for one, is directed to "several methods using IACs . . . for the detection of immunoassay completion" (Spec. 70: 1-3). In one such method, "the fluorescence signal (the timing signal) from a zone (the timing zone) downstream of the last detection zone [(the last assay zone)] was quantified" to determine assay completion (*id.* at 71: 2-4).

The rejection of the claims under 35 U.S.C. § 112, first paragraph, is reversed.

Obviousness

The Examiner rejected claims 27, 93, 94, 96, 99, 100, 109-116, 118, and 121-126 under 35 U.S.C. § 103(a) as unpatentable over Buechler and Van Deusen. In addition, the Examiner rejected claims 95 and 117 as unpatentable over Buechler, Van Deusen, and Slovacek; claims 28, 101, 102, 104, 107, 108, 127, and 128 as unpatentable over Buechler, Van

Deusen, and Foster; and claim 103 as unpatentable over Buechler, Van Deusen, Slovacek, and Foster.

We have carefully considered the Examiner's and Appellants' positions, but find that the evidence relied on by the Examiner is considerably stronger than is apparent from the rejections of record. Accordingly, we remand the application to the Examiner to reconsider the obviousness rejections in light of the following comments.

As discussed above, representative claim 27 is directed to an apparatus comprising an assay device, which in turn, comprises a reaction chamber containing an optically detectable label, in fluid communication with at least one diagnostic lane. Each diagnostic lane, in turn, comprises at least one assay zone and a separate timing zone. Because the reaction chamber and the diagnostic lane(s) are in fluid communication, a fluid sample added to the reaction chamber during the course of an assay reconstitutes the optically detectable label and carries it to the diagnostic lane(s), i.e., to the timing zone(s) and the assay zone(s). The claimed apparatus also includes an optical component configured to detect the signal generated by the optically detectable label in the timing zone(s), and generate an electronic signal in response, and a signal processor configured to receive the electronic signal, and determine the progress and time of completion of the assay.

As illustrated in Figure 1, Buechler discloses "diagnostic testing devices for determining the presence or amount of at least one target ligand" which comprise "various elements, [including] a sample addition zone **1**, a sample addition reservoir **2**, a sample reaction barrier **3**, a reaction chamber

4, a time gate **5**, a diagnostic element **6**, and a used reagent reservoir **7**" (Buechler, Fig. 1, and col. 4, l. 63, to col. 5, l. 3). The diagnostic element contains one or more capture zones, and "various means can be used for the detection of signal at the capture zone of the diagnostic element . . . [including] visual and instrumental means, such as spectrophotomeric and reflectance [means]" (*id.* at col. 11, ll. 21-31).

Focusing on Buechler's "time gate," (because the Examiner does), we note that Buechler teaches that "the time gate **5** holds the reaction mixture in the reaction chamber **4** for a given period of time . . . relative to the assay process such that the reactions which occur in the reaction chamber **4** as a result of the assay process will reflect the presence or amount of target ligand in the sample. Thus, the time gate **5** delays the flow of the reaction mixture onto the diagnostic element **6**" (Buechler, Fig. 1A, col. 7, ll. 41-53).

According to the Examiner, Buechler's assay device "meet[s] the requirements of the instant invention" (Answer 5), except for "the detailed structure of the optical system including an optical component and a signal processor" (*id.* at 6). The Examiner relies on Van Deusen as evidence that "devices having both an optical signal detector and [a] signal processor" are "conventional in the assay art" (*id.*). The Examiner asserts that Buechler's "time gate" reads on the "timing zone" of the present claims because Buechler's "'time gate' is in fluid communication with a diagnostic element (assay zone)" (*id.* at 12), it is separate from the assay zone, and it "houses the reaction mixture that includes signal-producing reagents" (*id.* at 13). Finally, the Examiner dismisses the claims' requirement for "an optical component configured to detect an optical signal generated from said label

in said . . . timing zone and generate an electronic signal in response" (e.g., claim 27) because "structural elements reading on 'configured to'[ ] are not recited in the rejected claim[s]" (*id.* at 14).

In this case, we agree with Appellants that "the 'configured to' language in the present claims is [not] mere surplussage that may be ignored" in interpreting the claims (Br. 16). Specifically, we agree with Appellants that the claims' requirement for "an optical component configured to detect an optical signal generated from said label in said at least one timing zone and generate an electronic signal in response" (e.g., claim 27) represents a structural limitation. That is, it requires a spatial relationship between two structural components of the claimed device - the "timing zone" (which is separate from the assay zone) and the "optical component" - such that the optical component can detect an optical signal generated within the timing zone, and generate an electronic signal in response.

The Examiner has not established that the "time gate" and the optical component of Buechler's device have the required structural, spatial relationship. While it is true that Buechler's "time gate" is in fluid communication with a reaction chamber and an assay zone, and in use, contains optically detectable label, Buechler's optical component is "not appropriately configured" (Br. 17), i.e., it is not in the correct position, to detect a signal from the optically detectable label within the time gate. Nor has the Examiner identified any reason that would have prompted one of skill in the art to combine, or configure, Buechler's time gate and optical component in the way the claimed invention does.

Nevertheless, as discussed above, Buechler's disclosure appears to be much more relevant to the patentability of the present claims than the Examiner appreciated.

In particular, we note that Buechler, in discussing the diagnostic element, and referring to Figures 1 and 2, teaches that "capture zones are comprised of reagents, such as receptors . . . which bind or react with one or more components from the reaction mixture. The binding of the reagents from the reaction mixture to the capture zones of the diagnostic element **6** is related to the presence or amount of target ligand in the sample" (Buechler, col. 10, ll. 10-19). These "capture zones" appear to be the same as the claimed "assay zones" because they are configured to bind analyte, the same function the "assay zones" are required to have by the claim. Moreover, Buechler's receptors "can be placed in discrete zones" (*id* at col. 10, ll. 21-23). In addition to the reagents that bind or react with the target ligand, Buechler teaches that "[r]eceptors or other chemical reagents, for example, a receptor against the signal generator can also be immobilized on the diagnostic element **6** to verify to the user that the reagents of the reaction mixture are viable and that the reaction mixture passed through the zones of the receptors or biosensors" (*id.* at col. 10, ll. 24-29).

In a further discussion of the diagnostic element, Buechler describes an assay wherein

> signal producing reagents, which could include, for example, a receptor specific for the target ligand adsorbed to a colloidal metal, . . . are placed . . . in the reaction chamber in dried or lyophilized form. Another receptor for each target ligand is immobilized onto the surface of the diagnostic element at the capture zone . . . The assay is then performed by addition of

> [the] sample . . . into the reaction chamber . . . The sample . . . dissolves the reagents in the reaction chamber to form the reaction mixture . . . The reaction mixture then moves past the time gate and onto the diagnostic element and over the capture zones. The complex of receptor conjugate and the target ligand formed in the reaction mixture binds to the respective receptor at the capture zone as the reaction mixture flows over the capture zones. *The reaction mixture may also flow over a positive control zone, which can be for example, an immobilized receptor to the signal development element* . . . [E]xcess sample moves onto the diagnostic element and removes the receptor conjugate which did not bind to the capture zone . . . [and] the signal at the capture zones can be interpreted visually or instrumentally.

Buechler, col. 14, ll. 25-66 (emphasis added).

These two passages, at least, appear to describe a positive control analogous to the independent assay control described in the present Specification. Moreover, Buechler's positive control appears to be designed to independently confirm that the assay reagents have actually passed over the capture zones, i.e., that the assay has run to completion. Since the signal producing reagent used to detect the target in the capture zone(s) is the same signal producing reagent that binds to the positive control zone, it is logical to assume that the capture zone(s) and the positive control zone are separate, discrete zones on the surface of the diagnostic element. Otherwise, the target and control signals would be indistinguishable. Moreover, it is logical to assume that Buechler's device is configured such that both the positive control zone and the capture zone can be accessed visually or instrumentally to determine whether the signal producing reagent has contacted both zones.

Upon return of this application, the Examiner is to determine whether these, or any other teachings of Buechler, are more relevant to the patentability of the present claims than the teachings presently relied on, and to reconsider the obviousness rejections of record accordingly.

SUMMARY

In summary, the rejections of claims 27, 28, and 93-128 under 35 U.S.C. § 112, first and second paragraphs, are reversed. The application is remanded to the Examiner for further consideration of the obviousness rejections.

This Remand to the Examiner pursuant to 37 C.F.R. § 41.50(a)(1) is made for further consideration of a rejection. Accordingly, 37 C.F.R. § 41.50(a)(2) applies if a supplemental examiner's answer is written in response to this Remand by the Board.

REVERSED; REMANDED

smsc

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